FEB 2 2 2001

K003423

ST. FRANCIS MEDICAL EQUIPMENT CO., LTD.

P.O.BOX 129 SHIEN CHUANG 24299,
TAIPEI SHIEN, TAIWAN, R.O.C.
FAX: 886-2-22783497, 22782799, 22775199
TEL: 886-2-22782889, 22783509, 22781618
E-MAIL: sthong@ms18.hinet.net

ISO 9002 EN 46002 KEMA
CERTIFIED FACTORY

"510(k) Summary"

Submitter's Name:	ST. FRANCIS MEDICAL EQUIPMENT CO., LTD.
Address:	No. 656-1, Sec 5 Chung Shin Rd., San Chung City, Taipei Hsien, Taiwan, ROC 241
Telephone:	886-2-22781555
FAX:	886-2-22783497
Contact Person:	Mr. Francis Hong
Date Summary Prepared:	2000/10/27
Proprietary Name:	Operating Theatre Lamps
Common Name:	Operating Theater Lamps
Classification Name:	Surgical Lamp
	(per 21CFR section 878.4580)
Device Class:	Class II (performance standards)
Specialty:	General & Plastic Surgery
Product code:	FTD
Legally Marketed (Predicate) Device :	ALM Prismatic Surgical Lights – K882613 Heraeus Hanalux 2000 – K895715

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Description of the new device:

LC-055 / OLH01-125 operating lamps provide appropriate illumination in the field or on patients in the surgical room by utilizing special features of halogen bulb with semi-transparent glass filter, 4-mm thick phosphated heat absorption glass, cover and delicate optical reflector to get the effects of eliminating glare without reducing illumination, to reduce 95% of the heat to produce the cool ray, to get better safety, higher transparency, and cool mirror.

The intended use of LC-055 / OLH01-125 is to provide visible illumination for the surgical field or on the patient.

Technological Characteristics of our new device compared to the predicate device:

The technological characteristics of ST. FRANCIS LC-055 / OLH01-125 operating lamp are substantially equivalent to those of ALM surgical lamps & Heraeus Hanaulux 2000, except for the different kinds of glass filters, i.e., Prismatic Lens & Fresnel Lens for the latter ones. ST. FRANCIS LC-055 / OLH01-125 operating lamps are of generally the same form and intended to be used in the same manner as the substantially equivalent products, i.e., ALM or Heraeus.

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Test Summary:

Two models of the operating lamps are in conformity with the following standards,

- *IEC 60601-1: 1988 Medical electrical equipment*

  Part I: General requirements for safety

- *IEC 60601-2-41: 2000 : Medical electrical equipment*

  Part 2-41:Particular requirements for the safety of surgical luminaries and luminaries for diagnosis

- *EN55011:1991+A1:1997+A2:1996 – Electromagnetic compatibility requirements EN 60601-1-2:1993, IEC801-2:1991, IEC801-3:1991, IEC801-4:1988, IEC801-5:1989*

ST. FRANCIS MEDICAL EQUIPMENT CO., LTD. believes this information and referred document to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate products and other products currently in distribution.

Francis

FRANCIS HONG

Submitter, October 27, 2000
General Manager
ST. FRANCIS MEDICAL EQUIPMENT CO., LTD.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2001

Mr. Francis Hong
St. Francis Medical Equipment Co., Ltd.
P.O. Box 129
Shien Chuang 24299
Taipei Shien, Taiwan, R.O.C.
China

Re: K003423
Trade Name: St. Francis Operating Theatre Lamp
Models OLH01-125 and LC-055
Regulatory Class: II
Product Code: FTD
Dated: February 8, 2001
Received: February 13, 2001

Dear Mr. Hong:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

Applicant: ST. FRANCIS MEDICAL EQUIPMENT CO., LTD.

510(k) Number (if known): ~~NA~~ K003423

Device Name: OPERATING THEATRE LAMPS, LC-055

Indications For Use:

To be used to provide visible illumination for the surgical field or on the patient in the operating room.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003423

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)